K014047

510(k) SUMMARY

FEB 2 8 2002

510(k) NUMBER: PENDING

SUBMITTED BY: Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA-92688
(949) 713-8000

CONTACT PERSON: Anil Bhalani
Vice President of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: December 6, 2001

NAME OF DEVICE: Laparoscopic Hand Access Port

CLASSIFICATION NAME: Laparoscope, General & Plastic Surgery.
(Regulation Number 21CFR 876.1500, Endoscope and accessories).

TRADE NAME: Applied GelPort Laparoscopic Hand Access Device

PREDICATE DEVICE:
1. Smith & Nephew Handport System (K990414), Smith & Nephew, Inc., Andover, MA.
2. Applied Intromit Laparoscopic Hand Access Port (K990663), Medtech Ltd., Ireland. Marketed by Applied Medical Resources, Rancho Santa Margarita, CA.

SUMMARY STATEMENT: The Applied GelPort Laparoscopic Hand Access Device is indicated for use in patients undergoing laparoscopic surgical procedures to obtain abdominal access by the surgeon's hand and instrumentation. Additional slits may be made using a trocar at the periphery of the Gel Seal Cap to allow instrument access to the surgical site. The Applied GelPort Laparoscopic Hand Access Device may be used in procedures such as nephrectomy, colectomy and splenectomy in colorectal, urological and general surgery to access the surgical site.. With the use of the Applied GelPort Laparoscopic Hand Access Device, the surgeon regains tactile sense and feedback along with the increased hand-eye and instrumentation manipulation capacity of open surgery. The device allows the surgeon multiple passages of the hand to access the surgical site without losing pneumoperitoneum. Instruments and Trocars may also be placed through the port in the center of the device and at the periphery of the device to allow instrument access to the surgical site, thereby reducing the need for additional incisions to the patient.

The device is designed with a slit for the hand at the center of the Gel Seal Cap. In addition to providing hand access, an instrument or trocar can also be inserted through this port during surgery to access the surgical site. The gel material conforms to the shape of the hand, instrument or trocar inserted through it providing a seal during laparoscopic surgery. Trocars can also be placed at the periphery of the Gel Seal Cap to allow for additional ports for instrument access during Hand Assisted Laparoscopy reducing the number of incisions required during surgery.

The Applied GelPort Laparoscopic Hand Access Device is very simple in design. It is simple to set up, easy to use and has a lower profile to maximize comfort. It consists of a Gel Seal Cap, a Base Ring Assembly, and a Retracting Sheath. The simple design makes installation of the Applied GelPort Laparoscopic Hand Access Device during clinical use very easy. Using a sterile skin marker an incision line is marked at the surgery site. Once the incision is made the retracting sheath is placed in position. The base ring assembly is then attached to the sheath. To complete the set up the Gel Seal Cap is snapped onto the base ring assembly. The sterile lubricant is provided to lube the surgeon's glove and the top of the Gel Seal Cap to make insertion of the hand into the port easy. Instruments may also be placed through the center slit if desired during surgery. If additional ports of entry are required for instrument access to the surgical site, slits can be made at desired locations on the periphery of the Gel Seal Cap using a non-threaded trocar. Instruments can then be inserted through the trocar cannula placed at the peripheral slit.

The Applied GelPort Laparoscopic Hand Access Device is a disposable, single-use device, packaged inside a PETG Tray with a Mylar peel cover, which is standard packaging material for medical products.

The Applied GelPort Laparoscopic Hand Access Device is substantially equivalent to predicate devices in design methodology, principle of operation and clinical utility. The Applied GelPort Laparoscopic Hand Access Device introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2002

Mr. Anil Bhalani
Vice President of Regulatory Affairs
and Clinical Programs
Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K014047
Trade/Device Name: Applied GelPort Laparoscopic Hand Access Device
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 6, 2001
Received: December 7, 2001

Dear Mr. Bhalani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Applied GelPort Laparoscopic Hand Access Device's "Indications for Use" as required.

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Device Name: Applied GelPort Laparoscopic Hand Access Device

Indications for Use: The Applied GelPort Laparoscopic Hand Access Device is indicated for use in patients undergoing laparoscopic surgical procedures to obtain abdominal access by the surgeon's hand and instrumentation. Additional slits may be made using a trocar at the periphery of the Gel Seal Cap to allow instrument access to the surgical site. The Applied GelPort Laparoscopic Hand Access Device may be used in procedures such as nephrectomy, colectomy and splenectomy in colorectal, urological and general surgery to access the surgical site.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhern (Optional Format 1-2-96)
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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